UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

JEANINE A. SORTISIO and STEVEN R. SORTISIO,

Plaintiffs,

v.

PETER ACCETTA, M.D., SUSAN M. PETERSON, RPA-C, ASTELLAS PHARMA US, INC., and NOVARTIS PHARMACEUTICALS CORPORATION,

Defendants.

Civil Action No.: _____

NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §§ 1331, 1441, and 1446, defendant, Astellas Pharma US, Inc. ("APUS") hereby files this Notice of Removal of this cause, with full reservation of all defenses, from the State of New York Supreme Court, County of Erie to the United States District Court for the Western District of New York. In support of this Notice, APUS states as follows:

1. Pursuant to Rule 81 (a)(3)(A) of the Local Rule of Civil Procedure, attached hereto as Exhibit A is an index of all documents filed in State Court.

2. On February 23, 2009, Plaintiffs Jeanine A. Sortisio and Steven R. Sortisio filed a products liability action against APUS, Novartis Pharmaceuticals Corporation ("NPC"), Peter Accetta, M.D. and Susan M. Peterson, RPA-C, in the State of New York Supreme Court, Erie County. The action is styled as *Jeanine A. Sortisio and Steven R. Sortisio v. Peter Accetta, M.D., Susan M. Peterson, RPA-C, Astellas Pharma US, Inc., and Novartis Pharmaceuticals Corporation*, Case No. I2009001945. Plaintiffs seek damages for injuries that

allegedly arose out of Jeanine Sortisio's use of APUS' prescription drug, Protopic®, and NPC's prescription drug, Elidel®.

3. APUS has not been served with the summons and Complaint. Upon information and belief, Plaintiffs also have not served the summons and Complaint on any other defendant in this case.[1] Accordingly, this Notice of Removal has been timely filed.

4 A copy of Plaintiffs' Complaint is attached as Exhibit B. Because no defendant has been served, there are no process, pleadings or orders to include with this Notice of Removal as required by 28 U.S.C. § 1446(a).

5. "Federal question" jurisdiction exists if federal law creates the cause of action, ***or*** if a plaintiff's "right to relief under state law requires resolution of a substantial question of federal law." *Franchise Tax Bd. of State of Cal. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 8-9 (1983); *see also Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005) ("[T]his Court [has] recognized for nearly 100 years that in certain cases federal question jurisdiction will lie over state-law claims that implicate significant federal issues.").

6. This Court has federal question jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1441 because Plaintiffs' claims require resolution of a substantial questions of federal law. Plaintiffs' claims are inextricably intertwined with, and also arise from, alleged violations of federal law, namely the federal Food Drug and Cosmetic Act ("FDCA") and the regulations thereunder. Accordingly, substantial federal issues are in dispute and the exercise of jurisdiction by this Court is consistent with congressional judgment about the sound division of

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[1] The consent of non-served or improperly served co-defendants is not necessary for removal. *See Varela v. Flintlock Constr., Inc.*, 148 F. Supp. 2d 297, 300 (S.D.N.Y. 2001); *Balazik v. County of Dauphin*, 44 F.3d 209, 213 (3d Cir. 1995); *Miranti v. Lee*, 3 F.3d 925, 929 (5th Cir. 1993); *P.P. Farmers' Elevator Co. v. Farmers Elevator Mut. Ins. Co.*, 395 F.2d 546, 547-48 (7th Cir. 1968); 14A Wright, Miller & Cooper, Federal Practice & Procedure § 3731 at 509-10 (1985).

labor between state and federal courts. *See, e.g., Grable*, 545 U.S. at 312 (2005) (holding that federal question jurisdiction exists notwithstanding the fact that Congress did not provide a private right of action); *see also Nicodemus v. Union Pac. Corp.*, 440 F.3d 1227, 1234-37 (10th Cir. 2006) (finding jurisdiction under *Grable* where state law claims required court to construe National Trails System Act); *Municipality of San Juan v. Corporacion Para El Fomento Económico De La Ciudad Capital*, 415 F.3d 145, 148 n.6 (1st Cir. 2005) (finding jurisdiction under *Grable* where propriety of defendant's conduct under state law "turn[ed] entirely on its adherence to the intricate and detailed set of federal regulatory requirements, and the funds at issue [were] federal grant monies"); *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 194-95 (2d Cir. 2005) (finding jurisdiction under *Grable* where state law claims required court to decide whether defendants violated Communications Act of 1934); *West Virginia v. Eli Lilly & Co.*, 476 F. Supp. 2d 230 (E.D.N.Y. 2007) (finding jurisdiction under *Grable* in case alleging state law claims against pharmaceutical company to recoup expenditures for drug under Medicaid program); *In re Zyprexa Prods. Liab. Litig.*, 375 F. Supp. 2d 170, 171-73 (E.D.N.Y. 2005) (finding jurisdiction under *Grable* where state law claims alleged pharmaceutical company improperly promoted drugs for off-label use in violation of the FDCA and its implementing regulations); *Becnel v. KPMG, L.L.P.*, 387 F. Supp. 2d 984, 986 (W.D. Ark. 2005) (holding that a substantial federal question existed where case rested on determination of legitimacy of investment plans and such determination required interpretation of federal tax law).

7. Plaintiffs' Complaint raises substantial federal questions because it alleges that NPC and APUS "improperly obtained approval for the drugs known as Elidel and Protopic from the United States Food and Drug Administration." *See* Compl. ¶ 13. The resolution of Plaintiffs allegations necessarily turns on the construction of federal law, namely whether NPC

and APUS violated the FDCA or the tangled web of FDA regulations governing the approval of prescription drug products. *See City of Chicago v. Int'l Coll. of Surgeons, Inc.*, 522 U.S. 156, 164 (1997) ("[E]ven though state law creates [a party's] causes of action, its case might still 'arise under' the laws of the United States if a well-pleaded complaint established that its right to relief under state law requires resolution of a substantial question of federal law.") (internal quotation marks omitted). Indeed, it will not be possible to determine whether Plaintiffs may prevail on their state law claims without first resolving these intricate issues of federal law. *See Hines v. Cenla Cmty Action Comm.*, 474 F.2d 1052, 1056 (5th Cir. 1973) ("A case arises under federal law if rights claimed by one party may be defeated by one construction of the statute and sustained by opposite construction."). Because Plaintiffs claims rely upon the interpretation and application of the FDCA and FDA regulations, and given that Plaintiffs may not defeat removal by failing to plead necessary federal questions, a federal court is the proper forum for addressing these claims.

8. Plaintiffs' Complaint also raises substantial federal questions because it alleges that the FDA-approved labeling for both Protopic® and Elidel® was inadequate, false, and misleading. *See* Compl. ¶¶ 14, 19, 23. Plaintiffs, therefore, have averred that APUS and NPC committed fraud on the FDA and directly challenge the FDA's decisions to approve Protopic® and Elidel® for marketing and to continue to allow APUS to market Protopic® and NPC to market Elidel® as labeled today.

9. Protopic® and Elidel® are currently marketed medications that are subject to extensive regulation by the FDA. Under the FDCA, the FDA is required to ensure that "drugs are safe and effective" for the intended uses, which is accomplished in part by "promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of

regulated products." 21 U.S.C. § 393(b)(1) and (b)(2)(B). Communications to physicians about Protopic® and Elidel® are contained within, and restricted by, labeling (such as the Package Insert) and promotional materials that are specifically approved and/or monitored by the FDA to ensure the provision of accurate information about the drugs' comparative risks and benefits.

10. In fact, on January 24, 2006, in connection with its new prescription drug labeling rule, the FDA provided a detailed and emphatic explanation of why its approval of product labeling preempts conflicting state law claims related to the adequacy of prescription drug warnings, noting that such claims frustrate "the full objectives . . . of Federal law." *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("FDA believes that under existing preemption principles, FDA approval of labeling under the act … preempts conflicting or contrary State law."). As recently as August 22, 2008, the FDA affirmed the position that its approval of product labeling preempts conflicting state law claims related to the adequacy of prescription drug warnings. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603, 49606 (Aug. 22, 2008) (noting that the "FDA reiterates and reaffirms" its position regarding preemption of state law claims regarding adequacy of approved labeling). Accordingly, there also is a substantial federal question with respect to whether Plaintiffs can claim, consistent with existing federal labeling requirements, that APUS and NPC failed to provide adequate warnings for Protopic® and Elidel® under state law.

11. Plaintiffs' Complaint further implicates federal law through allegations of improper marketing and advertising of Protopic® and Elidel®. Plaintiffs specifically allege that APUS and NPC "knowingly and negligently engaged in the deceptive . . . advertising [and]

promotion . . . of the drugs known as Elidel and Protopic." *See* Compl. ¶ 14. A substantial federal question is raised through allegations that a drug manufacturer violated federal regulations by improperly marketing a drug. *See In re Zyprexa Prods. Liab. Litig.*, 375 F. Supp. 2d 170, 171-73 (E.D.N.Y. 2005) (finding jurisdiction under *Grable* where state law claims alleged pharmaceutical company improperly promoted drugs for off-label use in violation of the FDCA and its implementing regulations).[2] Allowing individual state courts to make determinations regarding a pharmaceutical manufacturer's marketing of prescription drugs, which are heavily regulated by the FDA, would disrupt the federal regulatory scheme. The need for uniform interpretation and enforcement of the FDCA and FDA regulations underscores the appropriateness of removal of this action.

12. For the foregoing reasons, this Court has jurisdiction over this matter.

13. Pursuant to 28 U.S.C. § 1446(a), the United States District Court for the Western District of New York is the appropriate court for filing a Notice of Removal from the State of New York Supreme Court, County of Erie, where said action is pending. 28 U.S.C. § 112(d).

14. A copy of the written notification to state court, which is required by 28 U.S.C. § 1446(d), will be filed forthwith in the State of New York Supreme Court, County of Erie and served on Plaintiffs.

WHEREFORE, defendant, ASTELLAS PHARMA US, INC., hereby removes this action from the State of New York, Supreme Court, County of Erie, to the United States District Court for the Western District of New York.

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2 *But see Caggiano v. Pfizer Inc.*, 384 F. Supp. 2d 689 (S.D.N.Y. 2005) (holding that it lacked federal question jurisdiction over state-law claims of improper marketing and promotion).

DATED: Buffalo, New York
February 27, 2009

Respectfully submitted,

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